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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Anja EITRICH et al.

Confirmation No. 5886
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Examiner: Browe, David

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For : COSMETIC AND DERMATOLOGICAL SELF-TANNING FORMULATIONS COMPRISING DIHYDROXYACETONE AND GLYCERIN

AMENDMENT UNDER 37 C.F.R. § 1.111

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This is in response to the Office Action mailed from the U.S. Patent and Trademark Office on October 16, 2009, which sets a three-month shortened statutory period for reply to expire on January 19, 2010. Applicants hereby request an extension of time for one month and are concurrently filing a formal Request for Extension of Time, together with all requisite fees therefor. If for any reason the Request for Extension of Time is not associated with the file, or the fee submitted herewith is deemed insufficient for any reason, the present submission should be interpreted to include the requisite Request for Extension of Time, and the Patent and Trademark Office is hereby authorized to charge any fees necessary to preserve the pendency of this application to deposit account No. 19-0089.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1.- 33. (cancelled)

34. (new) A method of providing human skin with a natural tanned color, wherein the method comprises applying to human skin, in an amount which is sufficient to provide a tanned color, a cosmetic or dermatological self-tanning composition which comprises dihydroxyacetone and more than 5 % by weight, based on a total weight of the composition, of glycerin.

35. (new) The method of claim 34, wherein the composition comprises more than 8 % by weight of glycerin.

36. (new) The method of claim 34, wherein the composition comprises not more than 12 % by weight of glycerin.

37. (new) The method of claim 34, wherein a weight ratio of dihydroxyacetone and glycerin is smaller than 1 : 1.

38. (new) The method of claim 37, wherein the weight ratio is not higher than 0.9 : 1.

39. (new) The method of claim 38, wherein the weight ratio is at least 0.05 : 1.

40. (new) The method of claim 37, wherein the weight ratio is not higher than 2:3.

41. (new) The method of claim 37, wherein the weight ratio is at least 1 : 4.5.

42. (new) The method of claim 34, wherein the composition further comprises one or more O/W emulsifiers.

43. (new) The method of clam 42, wherein the one or more O/W emulsifiers comprise at least one emulsifier selected from polyethoxylated esters of fatty acids having a chain length of from 10 to 30 carbon atoms and a degree of ethoxylation of from 5 to 100 and esters of saturated, unbranched fatty acids with monomethoxylated glucose or polyglycerols.

44. (new) The method of claim 43, wherein the one or more O/W emulsifiers comprise at least one of a polyethoxylated ester of stearic acid and a polyethoxylated castor oil.

45. (new) The method of clam 42, wherein the one or more O/W emulsifiers comprise at least one emulsifier selected from sodium cetearyl sulfate, glyceryl stearate, glyceryl isostearate, glyceryl diisostearate, glyceryl oleate, glyceryl palmitate, glyceryl myristate, glyceryl lanolate and glyceryl laurate.

46. (new) The method of claim 42, wherein the composition further comprises at least one coemulsifier selected from fatty alcohols having a chain length of from 10 to 40 carbon atoms.

47. (new) The method of claim 46, wherein the at least one coemulsifier comprises cetearyl alcohol.

48. (new) The method of claim 34, wherein the composition comprises less than 5 % by weight of one or more UV filter substances, based on the total weight of the composition.

49. (new) The method of claim 34, wherein the composition comprises more than 8 % by weight of glycerin, a weight ratio of dihydroxyacetone and glycerin is smaller than 1 : 1, and the composition further comprises one or more O/W emulsifiers selected from polyethoxylated esters of fatty acids having a chain length of from 10 to 30 carbon atoms and a degree of ethoxylation of from 5 to 100, esters of saturated, unbranched fatty acids with monomethoxylated glucose or polyglycerols, and sodium cetearyl sulfate, glyceryl stearate, glyceryl isostearate, glyceryl diisostearate, glyceryl oleate, glyceryl palmitate, glyceryl myristate, glyceryl lanolate and glyceryl laurate.

50. (new) The method of claim 47, wherein the composition further comprises at least one coemulsifier selected from fatty alcohols having a chain length of from 10 to 40 carbon atoms.

51. (new) The method of claim 49, wherein the composition comprises not more than 12 % by weight of glycerin.

52. (new) The method of claim 47, wherein the weight ratio is not higher than 2 : 3.

53. (new) The method of claim 52, wherein the weight ratio is at least 1 : 4.5.

54. (new) The method of claim 34, wherein the composition is present as an oil-in-water emulsion.

55. (new) The method of claim 54, wherein a droplet size of an inner phase of the emulsion is larger than 500 nm.

56. (new) The method of claim 55, wherein the droplet size is larger than 1,000 nm.

REMARKS

Entry of the foregoing amendments is respectfully requested.

Summary of Amendments

Upon entry of the foregoing amendments, claims 11-33 are cancelled and claims 34-56 are added, whereby claims 34-56 will be pending, with claim 34 being the only independent claim.

Support for the new claims can be found throughout the present specification and in the cancelled claims. Regarding claims 36 and 51 submitted herewith it is noted that the highest percentage of glycerin in the exemplified compositions set forth at pages 21-24 of the present specification is 12 % by weight (see Examples 2, 6 and 10). The lowest weight ratio of dihydroxyacetone to glycerin in the exemplified compositions is 1 : 4.5 (see Example 4 and new claims 41 and 53), and the highest weight ratio is 2 : 3 (see Example 9 and new claims 40 and 52).

Applicants emphasize that the cancellation of claims 11-33 is without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute the cancelled claims in one or more continuation and/or divisional applications.

Summary of Office Action

As an initial matter, Applicants note with appreciation that the Office Action indicates that the claim for priority is acknowledged and that a certified copy of the priority document has been received by the Patent and Trademark Office from the International Bureau.

Applicants also note with appreciation that the Examiner has indicated consideration of the Information Disclosure Statement filed January 10, 2007.

Claims 11-31 and 33 are withdrawn from consideration.

Claim 32, i.e., the only claim under consideration, is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ziegler et al., U.S. Patent No. 5,232,688 (hereafter "ZIEGLER") in view of Scott et al., European Patent Application No. 0 884 045 A1 (hereafter "SCOTT").

Response to Office Action

Reconsideration and withdrawal of the rejection of record are respectfully requested, in view of the foregoing amendments and the following remarks.

The instant rejection under 35 U.S.C. § 103(a) essentially alleges that both ZIEGLER and SCOTT disclose a method as recited in rejected claim 32 but concedes that the generic lists of suitable glycols and polyols which are provided by these documents are too extensive to anticipate the specific and exclusive choice of glycerin.

Applicants respectfully traverse this rejection. In particular, it is pointed out that according to, e.g., the abstract of ZIEGLER the self-tanning compositions disclosed therein comprise as essential components (i) an α-hydroxy substituted ketone or aldehyde such as dihydroxyacetone, (ii) a polyacrylamide, and (iii) a pharmaceutically acceptable carrier. Additionally, these self-tanning compositions may optionally include at least 15 % of propylene glycol to improve color intensity.

Regarding the presence of propylene glycol, ZIEGLER states at col. 3, lines 4-13 thereof (emphasis added):

> Advantageously, there may also be incorporated propylene glycol at levels of at least 15% preferably between about 25 and 90%, optimally between about 25 and 45% by weight. Propylene glycol at these high levels was found to improve color intensity on the skin when combined with dihydroxacetone. Especially preferred is a combination of dihydroxacetone and propylene glycol in a weight ratio from about 2:1 to about 1:50. Preferably the weight ratio may range from about 1:1 to about 1:10, optimally about 1:8.

The body of the specification of ZIEGLER is completely silent with respect to compounds which may have a similar effect as that provided by propylene glycol. Only in Example 2 does ZIEGLER compare the color intensity imparting effect of propylene glycol with several other polyol compounds, i.e., glycerin, Carbowax 200, butylene glycol and diethylene glycol monoethyl ether. The comparison results set forth in Table 1 in col. 6 of ZIEGLER show that among the compounds tested glycerin in a concentration of 25 % by weight has the worst color intensity imparting effect of all polyol compounds tested. In particular, the color imparting effect of 25 % by weight of glycerin is worse than the color imparting effect of (i) 7.5 % and 25 % by weight of Carbowax 200, (ii) 48 % by weight of butylene glycol, (iii) 25 % by weight of diethylene glycol monoethyl ether and, above all (iv)12.5 % by weight (only 50 % of the tested concentration of glycerin) of propylene glycol, and much worse than the color imparting effect of 25 % by weight or higher concentrations of propylene glycol.

The above analysis is confirmed by col. 6, lines 32-38 of ZIEGLER:

> Based on the results listed in the Table, it is evident that propylene glycol has a color enhancing interaction with dihydroxacetone. Other glycols such as glycerine, butylene glycol and diethylene glycol monoethyl ether were operative but not to the same extent as propylene glycol. Levels of 45% propylene glycol were much more effective than lower levels.

In other words, ZIEGLER makes it abundantly clear that there is no compound and specifically, no polyol which can reasonably replace propylene glycol with respect to its color intensity imparting effect in the compositions taught therein. In view thereof, ZIEGLER not only fails to render it obvious to one of ordinary skill in the art to use glycerin instead of propylene glycol in the compositions disclosed therein, but even teaches away therefrom.

In this regard, it further is to be taken into account that instant claim 34 is drawn to a method of providing human skin with a natural tanned color. ZIEGLER fails to teach or suggest that propylene glycol (or glycerin) improves the natural tanned skin color tone provided by the self-tanning compositions taught therein but mentions only a color intensity imparting effect of these compounds, which does not provide any information as to whether the resultant tanned color would also look more natural. This is yet another reason why ZIEGLER fails to render obvious the claimed method.

SCOTT is unable to cure any of the deficiencies of ZIEGLER pointed out above. In particular, the compositions of SCOTT (which discusses the compositions of ZIEGLER in col. 4, lines 45-49 thereof) are significantly different from the compositions of ZIEGLER in that, *inter alia*, the former do not contain a polyacrylamide as critical component but instead must contain a polyethoxyglycol and a polyhydric compound having at least three hydroxyl groups and at least three carbon atoms (see, e.g., claim 1 of SCOTT). For this reason alone, one of ordinary skill in the art wishing to modify or improve the compositions of ZIEGLER would not be motivated to consult SCOTT in this regard.

At any rate, even if one were to assume, *arguendo*, that one of ordinary skill in the art would be prompted to include (at least) one of the critical components of the compositions of SCOTT, i.e., a polyhydric compound having at least three hydroxyl groups and at least three carbon atoms, in the compositions of ZIEGLER, the apparent choice would not be glycerin, let alone in a concentration of more than 5 % by weight.

Specifically, while glycerin is mentioned at, e.g., page 5, lines 54-58 of SCOTT as one of many examples of the polyhydric compound having at least three hydroxyl groups and at least three carbon atoms which is suitable for use in the compositions taught by SCOTT, this document also makes it clear that the preferred polyhydric compounds are D-sorbitol, D-mannitol and inositol, and in particular (D-)sorbitol, i.e., polyhydric compounds (sugar alcohols) which bear an only remote resemblance to glycerin. See, e.g., abstract, page 5, lines 57-58, page 6, lines 6-7, page 7, line 43, Examples 1-4, and claims 6, 11 and 22 of SCOTT.

Another reason to not add glycerin but one of the preferred compounds of SCOTT as the polyhydric compound having at least three hydroxyl groups and at least three carbon atoms to the compositions of ZIEGLER (if at all) is the fact that the (weak) color intensity imparting effect that is provided by glycerin (and possibly not provided by the preferred compounds of SCOTT) can be provided by other compounds which are also recommended by SCOTT as critical or at least optional components of the compositions disclosed therein.

For example, a critical component of the compositions of SCOTT is a polyethyoxyglycol, preferably ethoxydiglycol (= diethyleneglycol monoethyl ether). See, e.g., claims 1 and 4 of SCOTT. In this regard, it is pointed out that according to Table I in col. 6 of ZIEGLER diethyleneglycol

monoethyl ether has a better color imparting effect than glycerin. Accordingly, it would make much more sense to add one or more of the preferred polyhydric compounds having at least three hydroxyl groups and at least three carbon atoms of SCOTT and additionally, one of the other critical components of the compositions of SCOTT, i.e., diethyleneglycol monoethyl ether, instead of glycerin to the compositions of ZIEGLER (if at all).

Further, one of the recommended optional components of the compositions of SCOTT is a water soluble dihydroxyl compound having at least two and up to eight carbon atoms such as, e.g., propylene glycol. See, e.g., claims 7 and 10 and Examples 1-4 of SCOTT. Accordingly, SCOTT recommends the use of propylene glycol, i.e., the compound which according to ZIEGLER is the only polyol which can provide a strong color intensity imparting effect (much stronger than that provided by glycerin). In view thereof, the use of glycerin as the polyhydric compound having at least three hydroxyl groups and at least three carbon atoms of SCOTT as color intensity imparting compound in the compositions of ZIEGLER can apparently be dispensed with, which clears the way for adding to the compositions of ZIEGLER one of the preferred polyhydric compounds having at least three hydroxyl groups and at least three carbon atoms of SCOTT (if at all).

Regarding the concentration of the polyhydric compound having at least three hydroxyl groups and at least three carbon atoms of SCOTT it is noted that the preferred concentration thereof is from about 0.3 to about 5.0 % by weight, most preferred from about 0.5% to about 1.5% by weight (see, e.g., page 11, lines 22-25 of SCOTT). This is consistent with the compositions of Examples 1, 2 and 4 of SCOTT, which all contain 1 % by weight of sorbitol. The composition of claim 3 contains 3.5 % of sorbitol (5 % of a 70 % sorbitol solution).

This disclosure of SCOTT clearly does not prompt one of ordinary skill in the art to employ the polyhydric compound having at least three hydroxyl groups and at least three carbon atoms and in particular, glycerin in a concentration of more than 5 % by weight (as recited in present claim 34).

In this regard, it also is to be taken into account that according to SCOTT the maximum concentration of the polyhydric compound having at least three hydroxyl groups and at least three carbon atoms is 15.0 % by weight (see, e.g., claim 1 of SCOTT). Considering the fact that ZIEGLER shows that even at a concentration of 25 % by weight glycerin shows an only weak color intensity imparting effect, this is yet another reason why one of ordinary skill in the art would not be prompted by SCOTT to use glycerin instead of propylene glycol in the compositions of ZIEGLER.

Applicants submit that for at least all of the foregoing reasons, ZIEGLER in view of SCOTT is unable to render obvious the subject matter of any of the claims submitted herewith. Accordingly, withdrawal of the present rejection under 35 U.S.C. § 103(a) is warranted and respectfully requested.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
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